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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO |
|------------------------|-------------------------|----------------------|---------------------|-----------------|
| 10/676,678 | 10/01/2003 | Robert N. Golden | 61750-11 | 8202 |
| 22504 | 7590 11/02/2005 | | EXAMINER | |
| | RIGHT TREMAINE, L | ROY, ANI | URADHA | |
| | JRY SQUARE ΓΗ AVENUE | ART UNIT | PAPER NUMBER | |
| SEATTLE, WA 98101-1688 | | | 3736 | |

DATE MAILED: 11/02/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

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| | Application No. | Applicant(s) | | | | | |
|--|--|-----------------------|--|--|--|--|--|
| | 10/676,678 | GOLDEN, ROBERT N. | | | | | |
| Office Action Summary | Examiner | Art Unit | | | | | |
| | Anuradha Roy | 3736 | | | | | |
| The MAILING DATE of this communication app Period for Reply | ears on the cover sheet with the c | orrespondence address | | | | | |
| A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION. - Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication. - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely. - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication. - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b). | | | | | | | |
| Status | | | | | | | |
| 1) Responsive to communication(s) filed on Octo | <u>ber 24, 2005</u> . | | | | | | |
| 2a) ☐ This action is FINAL . 2b) ☑ This | action is non-final. | | | | | | |
| · | Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under <i>Ex parte Quayle</i> , 1935 C.D. 11, 453 O.G. 213. | | | | | | |
| Disposition of Claims | | | | | | | |
| 4) Claim(s) 1-26 is/are pending in the application. 4a) Of the above claim(s) 6,7,9 and 11-15 is/are withdrawn from consideration. 5) Claim(s) is/are allowed. 6) Claim(s) 1-26 is/are rejected. 7) Claim(s) is/are objected to. 8) Claim(s) are subject to restriction and/or election requirement. | | | | | | | |
| Application Papers | | | | | | | |
| 9) The specification is objected to by the Examine | г. | | | | | | |
| 10) The drawing(s) filed on is/are: a) acce | ☐ The drawing(s) filed on is/are: a)☐ accepted or b)☐ objected to by the Examiner. | | | | | | |
| Applicant may not request that any objection to the | Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a). | | | | | | |
| , | Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d). The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152. | | | | | | |
| | | | | | | | |
| Priority under 35 U.S.C. § 119 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f). a) All b) Some * c) None of: 1. Certified copies of the priority documents have been received. 2. Certified copies of the priority documents have been received in Application No 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)). * See the attached detailed Office action for a list of the certified copies not received. | | | | | | | |
| Attachment(s) | »□ | (DTO 443) | | | | | |
| Notice of References Cited (PTO-892) Notice of Draftsperson's Patent Drawing Review (PTO-948) Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date | 4) Interview Summary Paper No(s)/Mail Do 5) Notice of Informal P 6) Other: | | | | | | |

DETAILED ACTION

Oath/Declaration

The oath or declaration is defective. A new oath or declaration in compliance with 37 CFR 1.67(a) identifying this application by application number and filing date is required. See MPEP §§ 602.01 and 602.02.

The oath or declaration is defective because:

It does not identify the mailing address of each inventor. A mailing address is an address at which an inventor customarily receives his or her mail and may be either a home or business address. The mailing address should include the ZIP Code designation. The mailing address may be provided in an application data sheet or a supplemental oath or declaration. See 37 CFR 1.63(c) and 37 CFR 1.76.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 3-5, 8, 10, 16-18, 20, & 21-26 rejected under 35 U.S.C. 102(b) as being anticipated by Halls et al. (US Patent No. 6,428,551).

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Regarding claims 1, 10, & 18, Hall et al. discloses a medical device, as well as a method for detecting an encounter with an obstacle during insertion of a medical device, designed for insertion into a body, the device comprising: an elongated member (34) having a proximal end and a distal end for insertion into the body; and a location indicating element (24) flexibly coupled to the distal end of the elongated member and capable of being tracked from a location external to the body (Column 6, lines 28-41) wherein an encounter with an obstacle causes a change in the orientation of the location indicating element. Furthermore, Hall et al. discloses the location indicating element (24) is a permanent magnet (Abstract).

With regards to claims 3, 20, & 24, Hall et al. discloses a medical device and method further comprising a chamber (24) flexibly coupled to the distal end of the elongated member and having a predetermined orientation with respect to the elongated member wherein the location indicating element (comprised in 24, Column 1, lines 54-65) is contained within the chamber and wherein an encounter with an obstacle causes a change in the orientation of the chamber.

Regarding claims 4 & 21, Hall et al. further discloses a medical device comprising a flexible joint member (22) having first and second ends (Figures 1-4), the first end being coupled to the distal end of the elongated member (Figures 1-4) and the second end being coupled to the terminal chamber (Figures 1-4).

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Regarding claims 5 & 22, Hall et al. discloses a device wherein the flexible joint member has sufficient stiffness (Column 5, line 29) to maintain the orientation of the chamber under the influence of both gravity and the forces from flowing blood within a patient's vasculature.

Regarding claims 8, Hall et al. discloses a medical device wherein the flexible joint member (22) comprises a flexible metal member (Column 3, lines 57-60).

Regarding claims 16, 23, & 25, Halls et al. discloses a medical device wherein the elongated member is a selected one of a group comprising a tube, catheter (34 & Column 4, lines 21-22), guidewire, or other insertable medical device.

In regards to claims 17 & 26, Halls et al. discloses a medical device further comprising a detector system (Column 6, lines 28-41) capable of detecting the location indicating element from a location external to the body, the detector system including a display (Column 6, lines 30-33) to indicate an orientation of the location indicating element.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought

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to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 2 & 19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Halls et al. in view of Parsons et al. (US Patent No. 6,521,284).

Halls et al. discloses a medical device designed for insertion into a body with all of the elements listed above. However, Halls et al. does not disclose a device wherein the location indicating element is flexibly coupled to the elongated member using an elastic polymer. Parsons et al., however, teaches the use of an elastic polymer. It would have been obvious to one having ordinary skill in the art at the time the invention was made to flexibly couple the location indicating element to the elongated member using an elastic polymer in order "to increase the resiliency of the material" (Column 8, lines 54-58).

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Hall et al. (US Patent No. 6,733,511), Ferry et al. (US Publication No. 2004/0133130), Vilsmeter et al. (US Publication No. 2003/0114778), and Johnson et al. (US Patent No. 5,944,023) also discloses the use of magnetically navigable medical device.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Anuradha Roy whose telephone number is (571) 272-6169 and whose email address is anuradha.roy@uspto.gov. The examiner can

normally be reached between 8:00am and 4:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on 571-272-4726.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

~AR~

MAX F. MINDENBURG
AMSORY PATENT EXAMINER

LEANOLOGY CELITER 3700